

Remarks

The present response is submitted in reply to the Final Office action issued on January 25, 2010. Claims 1-7 and 10-16 are pending in this application. Claims 6, 10, 11 and 13-16 have been rejected and claims 1-5, 7 and 12 have been allowed. The Applicants thank the Examiner for concluding that claims 1-5, 7 and 12 contain allowable subject matter. By the present response, claims 10, 11 and 13 have been amended to clarify certain indefinite issues, as addressed more specifically below. Support for the amendments may be found throughout the specification and in the claims as filed, as acknowledged by the Examiner in the Final Office action.

No new matter has been added. Reconsideration is respectfully requested in light of the amendments being made hereby and of the following remarks.

Rejection of claims 10, 11, 13-16 under 35 U.S.C. 112, first paragraph

Claims 10, 11, 13-16 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner states that claims 10 and 13 recite “gel” and that, while there is support in the specification to recite “gel-like,” there is no support to recite “gel.” The Examiner also states that claims 11 and 13 recite “powdery preparation,” and that, while there is support in the specification to recite “powdery materials,” there is no support to recite “powdery preparation.”

The Applicants submit that the claims have been amended accordingly. Therefore, withdrawal of this rejection is requested.

Rejection of claims 6, 11, 13-16 under 35 U.S.C. 112, second paragraph

Claims 6, 11, 13-16 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. In particular, the Examiner states that claim 6 recites “gel-like,” but that “like” renders the recitation ambiguous. The Examiner also states that it is unclear what is meant by “powdery preparation” in claims 11 and 13.

In this regard, the Examiner states that if the Applicants clarify on the record what is intended to be meant by the term “gel-like,” then the Examiner will reconsider the rejection. The Applicants submit that the recitation “gel-like” is employed simply as an adjective of “gel” (analogous to “powdery”). Accordingly, the term “gel-like” would clearly mean to one skilled in the art “having the appearance and consistency of a gel.” In the same sense, the term “powdery” would clearly mean to one skilled in the art “having the appearance and consistency of a powder.”

Withdrawal of this rejection is requested.

Rejection of claim 13 under 35 U.S.C. 103(a)

Claim 13 has been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,244,677 (Kreckel, et al.) in view of U.S. Patent Nos. 3,655,918 (Lindquist, et al.), 5,716,636 (Horstmann, et al.) and 4,415,124 (Carduck, et al.), and further evidenced by U.S. Patent No. 4,650,817 (Allen Jr., et al.). According to the Examiner, Kreckel, et al. teach a transdermal drug delivery device (i.e., bandage strips) having a drug formulation that is stored in a punched-out cavity of foam material, such as

polyethylene foam layer 18. Additionally, according to the Examiner, the adhesive die-cut article of Kreckel, et al. has an external contour which comprises adhesive layer 19 with an internal cut-out having a contour, wherein the external contour of the adhesive die-cut article has no common point with the contour of the internal cut-out. The Examiner further states that the die-cut article of Kreckel, et al. has a layer of foam having punched out reservoir having an internal cut-out which is congruent with the internal cut-out in the adhesive layer, as well as a protective film (i.e., covering film) covering the composite of matrix layer, adhesive layer and the internal cut-out.

The Examiner further states that Kreckel, et al. teach “In Figs. 8 and 9 ... for a transdermal delivery of low-viscous micro-emulsion containing the particular drugs. These micro-emulsions are contained in a material piece (22) of absorbent material placed in a punched out reservoir (21) ... closed cells.”

The Examiner’s position is that the difference between the claimed invention and Kreckel, et al. is that Kreckel, et al. is silent as to teaching the foam layer (matrix layer) being a compacted material, specific pharmaceutical active ingredient and the filler material. However, the Examiner refers to Lindquist, et al. for teaching a conformable adhesive sheet that has improved conformability and splitting resistance and can be used as surgical drape or as a bandage, and that the surgical tape of Lindquist, et al. comprises compressed foam web which the Examiner interprets to meet the present claim requirement of “matrix layer being a compacted material.” The Examiner also interprets the disclosure of Lindquist, et al., with respect to the compression of foam, that such compression improves splitting resistance of the adhesive tape.

Allen Jr., et al. is referenced to show that in adhesive bandage dressing art, polyethylene foam and polyurethane foams are functionally equivalent in the formation of backing.

The Examiner thus concludes that it would have been obvious to provide the matrix layer of Kreckel, et al. as being a compacted material, motivated by the desire to provide sufficient tensile strength and to provide enhanced peel and splitting resistance.

The Examiner also states that Kreckel, et al. as modified by Lindquist, et al. is silent as to teaching the specific pharmaceutical active ingredient. However, the Examiner refers to Horstmann, et al. for teaching a transdermal therapeutic system comprising active substance acetylsalicylic acid. In this regard, the Examiner concludes that it would have been obvious to select the pharmaceutical active ingredient such as acetylsalicylic acid as taught by Horstmann, et al. and used in the invention of Kreckel, et al. because selection of a known material based on its suitability for its intended use establishes *prima facie* obviousness.

The Examiner further states that Kreckel, et al. and Horstmann, et al. are silent as to teaching the specific filler as presently claimed. The Examiner thus refers to Carduck, et al. for disclosing a method for the production of micropowders and that the powders can be used as vehicles (equated to the Applicant's filler being powdery preparation) for drugs in the pharmacy. The Examiner also states that the powder of Carduck, et al. is a fusible material. Thus, the Examiner concludes that it would have been obvious to select the powders as fillers as taught by Carduck, et al. in the invention of Kreckel, et al. so as to use the powders as vehicles, since it has been held that selection of a known material

based on its suitability for its intended use establishes *prima facie* obviousness and that given that the size distribution of the powder effects the rate dissolution, it would have been obvious to select powders as fillers in order to control the release of the drug.

The Applicants respectfully submit that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. The Applicants submit that each and every feature recited in the present claims, as amended herein, are not set forth in Kreckel, et al. alone or in combination with the other cited prior art. Moreover, the Applicants do not believe one skilled in the art would have had any motivation to amend or modify the invention of Kreckel, et al. to arrive at the presently claimed invention.


As noted above, the Examiner has referred to Carduck, et al. for teaching powdery preparations and fusible materials for use as a filler material. However, it is submitted that the use of a gel-like material (i.e., a material having the appearance and consistency of a gel) is not taught or disclosed in any of the cited prior art. Thus, each and every feature of the present invention as recited in the claims is not set forth in the combination of teachings of the prior art references. Therefore, withdrawal of this rejection is strongly requested.

Conclusion

In light of the foregoing claims and arguments, it is believed that the present application is in condition for allowance, and such action is earnestly solicited. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

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